K123378

3. 510(k) Summary

NOV 30 2012

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Larry Boucher Sr. Regulatory Affairs Specialist Telephone: (949) 297-9781 E-mail: larry.boucher@covidien.com
Date Summary Prepared:	27 November 2012
Trade Name of Device:	Solitaire™ 2 Revascularization Device
Common Name of Device:	Catheter, Thrombus Retriever
Classification of Device:	21 CFR 870.1250 – Class II
Predicate Device:	Solitaire™ FR Revascularization Device (K113455)
Device Description:	The Solitaire™ 2 device is designed to restore blood flow in subjects experiencing ischemic stroke due to large intracranial vessel occlusion within 8 hours of symptom onset. It is indicated for subjects who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy. The distal nitinol portion of the device facilitates clot retrieval and has Pt-Ir radiopaque markers on the proximal and distal ends. The following modifications have been made to the device in support of this application: • The attachment zone has been redesigned for greater tensile strength. • The marker band has been redesigned to aid the crimping process. • The pushwire now contains a fluorosafe marker. • The Solitaire™ 2 Device uses one piece of PTFE tubing.
Intended Use:	The Solitaire™ 2 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Performance Data: The following tests were performed to support the changes to the Solitaire™ 2 Revascularization Device:

Non-Clinical

Bench Testing:

- Delivery Force
- Withdrawal Force
- Total System Length
- Fluoro Safe Marker Length
- Distal Tip to Fluoro Marker Length
- Durability
- Radiopacity
- Torque Response
- Torque Strength
- System Tensile

1-Year Accelerated Aging Study

- Delivery Force
- Withdrawal Force
- Durability
- Torque Response
- Torque Strength
- System Tensile Strength

The following tests were not performed as they are not related to the changes being made to the Solitaire™ 2 Revascularization Device:

Bench Testing:

- Kink Resistance
- Marker Coil Tensile Strength
- Radial Force

In addition, no clinical or animal testing was performed as there is no change in the indications for use or the fundamental scientific technology of the device.

Conclusion: The Solitaire™ 2 device is substantially equivalent to the Solitaire™ FR Revascularization Device based on the successful completion of non-clinical testing as well as identical principles of operation, materials of construction, dimensions, packaging, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 30, 2012

Micro Therapeutics DBA ev3 Neurovascular
c/o Mr. Larry Boucher
Senior Regulatory Affairs Specialist
9775 Toledo Way
Irvine, CA 92618

Re: K123378
Trade/Device Name: Solitaire 2 Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Thrombus Retriever
Regulatory Class: Class II
Product Code: NRY
Dated: October 29, 2012
Received: November 1, 2012

Dear Mr. Larry Boucher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Quynh T. Hoang for:

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K123378

Device Name: Solitaire™ 2 Revascularization Device

Indications For Use:

The Solitaire™ 2 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Prescription Use __XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Quynh T. Hoang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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